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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,000	01/04/2007	Olivia Niebla Perez	976-31 PCT/US	5827
23869 7590 08/04/2009 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER ARCHIE, NINA	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,000	Applicant(s) NIEBLA PEREZ ET AL.	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/14/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 4-14-09.

Election/Restrictions

2. Applicant's election without traverse of Group I claims 1-4 are acknowledged.
Claims 1-12 are pending. Claims 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group 2, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on 3/23/2009. Claims 1-4 are currently under examination.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

6. The information disclosure statement filed 8/8/2007 has been considered. An initialed copy is enclosed.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4 rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al WO 2003/051379 Date June 26, 2003, Uchida et al 1979 J. Cell Biology Vol. 80 pgs. 10-20, and Mayer et al 1999 Progr Colloid Polym Sci Vol. 113 pgs. 176-181.

Claims 1-4 are drawn to a method for antigen incorporation into bacterial outer membrane vesicles characterized by the formation of a complex between these antigens and outer membrane proteins from gram-negative bacteria, while maintaining intact the vesicle structure and comprising:

- Dilution of the antigen to be incorporated in an aqueous solution containing detergents and sucrose

- Homogenization of such a solution with the bacterial outer membrane protein preparation

- Incubation of the homogenate for at least 4 hours, with stirring

- Ultracentrifugation of the homogenate to recover the outer membrane vesicles containing the incorporated antigen

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-Suspending the pellet in an appropriate solution (claim 1);
the method, wherein the outer membrane protein preparation is obtained from gram-negative bacteria belonging to the Neisseriaceae family or from *Branhamella catarrhalis* (claim 2), wherein the outer membrane protein preparation is obtained from *Neisseria meningitidis* and *Neisseria lactamica* (claim 3), wherein said protein antigen is of natural, recombinant or synthetic origin (claim 4).

Foster et al teach a method of preparing a composition from a mixture of outer membrane vesicles (OMVs) from Gram negative bacteria such as *Neisseria meningitidis* comprising a heterologous antigen (see abstract pgs. 1-2 and claims). Foster et al teach direct combination *in vitro* where an energetic combination step can optionally be applied to facilitate integration of an antigenic component into OMVs compartments with methods including homogenization, ultrasonication, extrusion and combinations thereof (see pg. 6 lines 30-35). Foster et al teach a method for extracting OMVs with detergent deoxycholate in a buffer containing sucrose (see Example 1).

Foster et al differs from the instant invention in that they do not explicitly teach method steps comprising the use of the antigen as instantly claimed aforementioned above.

Uchida et al teach the formation of liposomes containing an antigen (fragment A with HVG spikes). Uchida et al teach an antigen (Sendai virus (HVJ spikes)) prepared in buffer containing sucrose (see pg. 12 column 1 last paragraph). Uchida et al teach lipids prepared and added to the mixture comprising the antigen and sucrose as set forth *supra* which was solubilized with a detergent 0.85% NP40.

Uchida et al teach the solution of the antigen and lipids dialyzed for 6 days (see pg. 12 column 2 paragraph 1). Uchida et al teach applying the turbid suspension to a Bio-Gel for purification and further purification was accomplished by centrifugation through a linear sucrose gradient in buffer (see pg. 12 column 2 paragraph 1).

Furthermore given that the use OMVs to deliver heterologous antigens and methods for preparing the same is well known in the art leading to predictable results, it would have been *prima facie* obvious at the time of the invention to combine the teachings of Foster et al. and Uchida et al.

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Moreover, Mayer et al demonstrates that sucrose is known in the art for stabilizing proteins, and when used in conjunction with a detergent is an effective solution for solubilizing proteins. Consequently, their use is also deemed to be obvious.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

Examiner

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/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645